UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/236,985	08/26/88	COOPER	G 183/272

EXAMINER
LEE, L

LYON & LYON
611 WEST SIXTH STREET, 34TH FLOOR
LOS ANGELES, CA 90017

ART UNIT	PAPER NUMBER
189	13

DATE MAILED: 12/10/90

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on Sept. 20, 1990 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
5. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 2-4, 6-18, 20-21, 23, 29-31, 34-40, 43-45 and 46-75 are pending in the application.
   Of the above, claims 2-4, 6-18, 20-21, 23, 29-31 and 34-40, 43-45 are withdrawn from consideration.
2. ☒ Claims 1, 5, 19, 22, 24-28, 32-33 and 41-42 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 46-75 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 189B.

Claims 2-4, 6-18, 20-21, 23, 29-31 and 34-40 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being for a nonelected invention. In view the restriction requirement of paper no. 6 was made final in paper no. 9, applicant is required to either cancel these claims in their next response or take other appropriate action.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 46-75 are rejected under 35 U.S.C. § 101 because the invention as disclosed in inoperative and therefore lacks utility.

Applicant's have alleged that the compositions are effective in the treatment of Diabetes mellitus or hypoglycemia. However, the disclosure contains no in vivo data or effective dosages that support that the treatment with the compositions are effective. Since the alleged utility is unbelievable upon its face, applicant must have supportive data (in vivo experimental or

clinical data) to overcome the above rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant has not enable one skilled in the art how to use the compositions effectively in the treatment of Diabetes Mellitus or hypoglycemia. See above paragraph of lack of utility for further explanation or rejection.

Also, applicant's disclosure is not enabling as to the preparation and identification of the active subfragment(s), conservative variants or functional peptides of amylin.

Claims 46-75 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Applicant's principle arguments as to the above rejections appear to be (1) that the specification at pp. 12-13 and the experiments described show that amylin reduces the rate of

glycogen synthesis in rat soleus muscle strips and therefore, it appears that the co-administration of amylin with insulin may avoid the serious side effect of hypoglycemia associated with treatment with insulin alone, and (2) that the Examiner has not provided support for his statement that "since products are intended for in vivo treatment, applicant must have data showing operability in vivo".

These arguments have been duly considered but are not persuasive.

Since it is well known in the art that the effective treatment of diabetes by pharmaceutical compositions has only been accomplished by the use of insulin, the allegation that a new composition is effective is unbelievable upon its face. Applicant has stated in the amendment that "the co-administration of amylin with insulin may avoid the serious side effect of hypoglycemia associated with treatment of insulin alone. This statement implies that the compositions have not been tested and that they may or may not be effective. This statement does not satisfy the requirements of 35 USC 101 of utility or 35 USC 112, paragraph one of teaching how to use the compositions effectively to treat Diabetes mellitus or hypoglycemia.

Furthermore, Applicant's claimed compositions do not include insulin and therefore an argument as to a composition containing amylin and insulin together is not pertinent as to the

effectiveness of amylin alone.

Applicant's claimed compositions can have many different compounds in place of amylin, e.g. CGRP, denominated CGRP, reduced CGRP, amylin peptide fragments, conservative variants of amylin, CGRP peptide fragments or conservative variants of CGRP. Applicant's disclosure has not shown that any of this compound in a pharmaceutical composition are effective.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 56-65 are rejected under 35 U.S.C. § 103 as being unpatentable over pages 10-11 of Applicant's specification.

Applicant's specification teach that the claimed compositions are prepared by the conventional methods well known in the art. See In re Durden 226 USPQ 359.

Claims 46-75 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected for the following reasons:

(a) the terms "compound having amylin-like activity", "peptide" "functional amylin peptide fragment", "conservative variant of amylin", "CGRP peptide fragment", and "conservative variant of CGRP" are indefinite as to the scope of compounds included in the claims and;

(b) claims 56-65 are functional as to the point of novelty since the process is defined as bringing an effective amount of a compound into the form of a composition suitable for therapeutic administration. The claims do not set forth th process steps of how the compositions are prepared.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE

MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Lester L. Lee at telephone number (703) 308-0196.

Lee/th
December 3, 1990

LESTER L. LEE
PRIMARY PATENT EXAMINER
ART UNIT ~~186~~ 189